UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,448	12/30/2003	Jeff Ondrla	1671-0285	2398

28078 7590 06/09/2006

MAGINOT, MOORE & BECK, LLP
CHASE TOWER
111 MONUMENT CIRCLE
SUITE 3250
INDIANAPOLIS, IN 46204

EXAMINER	
BLANCO, JAVIER G	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,448	ONDRLA ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,7 and 12-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,7 and 12-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 1, 3, and 7 in the reply filed on March 21, 2006 is acknowledged.

2. Applicants' cancellation of claims 2, 4-6, and 8-11 in the reply filed on March 21, 2006 is acknowledged.

3. Applicants' addition of claims 12-18 in the reply filed on March 21, 2006 is acknowledged.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "said fastener" (see line 2 and line 3) lacks antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 7, and 12-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bahler (WO 2001/22905; previously cited by the Examiner). For English translation see US 6,749,637 B1.

Referring to Figure 1, Bahler discloses a shoulder joint prosthesis comprising:

(a) A stem (stem 13 of shaft 11), said stem defining a first coupler bore having a proximal bore segment (bore 25) and a distal bore segment (threaded bore 31);

(b) A joint component (cap 65) having a bearing surface (surface 75) and defining a second coupler bore (conical indentation 83);

(c) A mounting element (directional piece 41) having (i) a proximal portion (conical face 45) received within said second coupler bore of said joint component in a friction fit manner, and (ii) a spherical articulating portion (articulating face 43) received within said first coupler bore of said stem;

(d) A fastener (screw 53) located within said proximal bore segment and said distal bore segment, and having an externally threaded shaft (threaded portion 57) which engages internal threads located within said distal bore segment (threaded bore 31) of said first coupler bore; and

(e) Wherein said proximal bore segment, when viewed in a cross-section, further includes a linearly extending interior wall is formed thereon, and wherein said spherical articulation portion of said mounting element contacts (via rotating piece 33) said linearly extending interior wall. The bearing surface of said joint component mates with a glenoid component (85).

8. Claims 12-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Glien et al. (DE 101 23 517 C1; cited in Applicants' IDS).

Referring to Figures 1-8 (particularly Figures 3-5), Glien et al. disclose a joint prosthesis comprising:

a. A stem (stem 12) having a bone engagement portion and a surface facing the mating component of the joint, said surface defining a tapered bore (cavity 14 is tapered at 15, 16, 17, and its distal end);

b. A head component (head 40) having a bearing surface (see Figures 3-5) and a tapered cavity (tapered cavity 41);

c. A mounting element (character 20) having a proximal portion (tapered block 21, 28) *configured for engagement* (emphasis added to functional language) with said head component and an articulating portion (hemispherical ball joint 23) defining a spherical bearing surface sized *to be received* (emphasis added to functional language) within said tapered bore and *to form* (emphasis added to functional language) a friction-fit engagement with said bore when said articulating portion is pushed into said bore, the mounting element further having a passageway (cavity 24) through said mounting element with an inner bearing surface (surfaces 25, 26, and tapered surface between the proximal end and distal end of cavity 24) at said articulating portion; and

d. A screw (screw 30) extending from said mounting element *for engagement* (emphasis added to functional language) to the stem when said articulating portion is disposed within said tapered bore. Said screw comprises a cylindrical rod 31 having threaded end 33 formed therein. Said screw further includes an underside *configured for articulating contact* (emphasis added to functional language) with said inner bearing surface (surfaces 25, 26, and tapered surface between the proximal end and distal end of cavity 24) of the mounting element. The spherical

bearing surface of said mounting element for contacting said bore to permit movement of said mounting element in multiple degrees of freedom (see Figures).

Response to Arguments

9. With regards to the 102(b) rejection based on Glien et al. (DE 101 23 517 C1; cited in Applicants' IDS), Applicants' arguments filed March 21, 2006 have been fully considered but they are not persuasive. The Applicants argue that Glien et al. does not disclose or suggest: "said mounting element contacts said linearly extending interior wall of said stem". The Examiner respectfully disagrees. As best seen in Figures 3-5, the spherical articulating portion contacts a linearly extending (when viewed in cross-section) interior wall (see how the interior wall is divided in small linearly extending wall portions).

10. Claims 1, 3, 7, and 12-18 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Horber (WO 2003/096939 A1; previously cited by the Examiner). For English translation see US PG Pub No. 2005/0113931 A1.

Referring to Figures 1, 3, and 6-10, Horber discloses a shoulder joint prosthesis comprising:

(a) A stem (stem 19), said stem defining a first coupler bore (articulation cavity 21) having a proximal bore segment (the one comprising lateral surface 25) and a distal bore segment (threaded bore 31);

(b) A joint component (cap 50) having a bearing surface and defining a second coupler bore (see Figure 8);

(c) A mounting element (articulation body 15) having (i) a proximal portion (conical surface 47) received within said second coupler bore of said joint component in a friction fit manner, and (ii) a spherical articulating portion (see Figures 1, 3, 6, and 9) received within said first coupler bore of said stem;

(d) A fastener (locking screw 17) located within said proximal bore segment and said distal bore segment, and having an externally threaded shaft (threaded section 33) which engages internal threads located within said distal bore segment (threaded bore 31) of said first coupler bore; and

(e) Wherein said proximal bore segment, when viewed in a cross-section, further includes a linearly extending interior wall (see lateral surface 25) is formed thereon, and wherein said spherical articulation portion of said mounting element contacts said linearly extending interior wall. The bearing surface of said joint component mates with a glenoid component (52).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1, 3, 7, and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. (US 6,228,120 B1; cited in Applicants' IDS) in view of in view of Horber (WO 02/39932 A1).

Referring to Figures 1-9 (particularly Figures 1-3), Leonard et al. disclose a joint prosthesis comprising:

a. A stem (stem 1) having a bone engagement portion (rod 2) and a surface (frontal face 4 of metaphysical section 3) facing the mating component of the joint, said surface defining a bore (cavity 7) and a threaded bore (threaded bore 8) aligned with said bore;

b. A head component (head 20) having a bearing surface (see Figures 1-3) and a tapered cavity (tapered cavity 21);

c. A mounting element (tapered swivel 12 + hemispherical ball joint 10) having a proximal portion (tapered swivel 12) *configured for engagement* (emphasis added to functional language) with said head component (see columns 6 and 7) and an articulating portion (hemispherical ball joint 10) defining a spherical bearing surface sized *to be received* (emphasis added to functional language) within said bore (see columns 5 and 6) and *to form* (emphasis added to functional language) a friction-fit engagement (see column 6, lines 25-31) with said bore when said articulating portion is pushed into said bore, the mounting element further having a passageway (cavity 14) through said mounting element with an inner hemispherical bearing surface (hemispherical surface 10b) at said articulating portion; and

d. A screw (locking unit 16) extending from said mounting element *for engagement* (emphasis added to functional language) to said threaded bore (see columns 6 and 7) when said articulating portion is disposed within said bore. Said screw comprises a cylindrical rod 17 having threaded end 17a formed therein. Said screw further includes hemispherical ball joint 18 (underside of head 19) *configured for articulating contact* (emphasis added to functional language) with internal/inner hemispherical surface 10b of hemispherical ball joint 10. The spherical bearing surface of said mounting element for contacting said bore to permit movement of said mounting element in multiple degrees of freedom (see column 8, line 61 to column 9, line 24). The method

for mounting said joint component to a bone is disclosed at column 8, line 48 to column 9, line 36. The method (particularly, position adjustment) could be performed with or without using a trial implant (see column 9, lines 37-48).

Leonard et al. disclose the invention as claimed except for particularly the spherical articulating portion of said mounting element as contacting a linearly extending interior wall within a first coupler bore. However, this is well known in the art. For example, Horber (see US 6,818,019 for English translation) disclose a joint prosthesis comprising a spherical bearing/articulation surface pressed into either a square/cylindrical (Figure 2), polygonal (Figure 3), spherical (Figure 8), or tapered (Figures 1 and 6) bore (cavity 19) in order to permit movement of a mounting element (joint head 25) in multiple degrees of freedom (see Figures; see entire document). Horber's WO 02/39932 is evidence that, with regards to permitting movement of a mounting element in multiple degrees of freedom, square/cylindrical bores, polygonal bores, spherical bores, or tapered bores are functionally equal and interchangeable. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a stem comprising a tapered bore, as taught by Horber, with the stem of Leonard et al., in order to permit movement of Leonard et al.'s hemispherical ball joint 23 in multiple degrees of freedom.

Response to Arguments

13. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

June 3, 2006

David H. Willse
Primary Examiner